Results: 85 patients who met the selection criteria were analyzed. The demographic features were - males 61%; Caucasians - 54%; African Americans - 38%; history of pulmonary disorder- 41%; NSCLC- 78%; PS- 0,1- 92%; Stage III- 89%. The median dose of TR was 5940 cGy. Radiation fields have been retrospectively assessed in 41 patients to date. 9 of the 41 patients (22%) received involved field radiation. 53 patients (63%) received Cisplatin/Etoposide and 20 patients (24%) received Carboplatin/Paclitaxel. 75 patients (88%) received concurrent therapy. 31 patients (36%) developed RP; 15 (18%) had RTOG grade ≥ 3 RP. Median time to development of RP was 4.6 months. Rate of RP in females and males was 42% vs. 33% (p=0.49). Rate of RP in patients with history of pulmonary disorder at baseline was 49% as compared to 28% in others (p=0.068). 1 year hospitalization rate was 74% and 37% in RP and non-RP patients (p=0.0015). For all 85 patients, the median overall survival (OS) was 19.5 months (95% CI 16.4 - 23.3). Length of OS did not differ significantly (p = 0.59) between the 31 patients who had RP vs. the 54 patients who had no RP (median OS: 19.3 vs. 18.8 months, respectively). The median survival of the 15 patients who had severe RP was 16.6 months.

Conclusions: The rate of severe RP in these 85 lung cancer patients, treated off-protocol with CT and TR, is higher than that reported in clinical trials. Despite higher morbidity (i.e., increased hospitalization) in patients with RP, survival duration did not differ significantly by RP status.

P2-221 **NSCLC: Combined Modality Therapy Posters, Tue, Sept 4**

Adjuvant docetaxel plus carboplatin versus observation in patients with completely resected stage IB-IIIA non-small-cell lung cancer: preliminary results of the Chinese Society of Lung Cancer randomised controlled trial (CSLC201)

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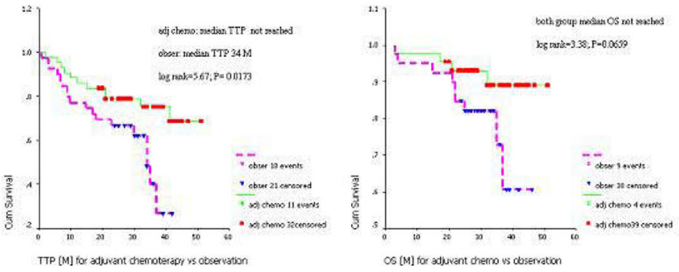
Background: Four larger clinical trials, IALT, NCIC-JBR10, ANITA and Japanese UFT trial, have shown significant OS advantages with adjuvant chemotherapy. Unless vinorelbine plus cisplatin, whether other third generation doublet chemotherapy regimen improves survival of patients with non-small-cell lung cancer (NSCLC) is not known. We aimed to compare the effect of adjuvant docetaxel plus carboplatin versus observation on survival in patients with completely resected NSCLC.

Methods: 82 patients with stage IB-IIIA NSCLC from 3 centres in China were randomly assigned to 75mg/m(2) docetaxel plus AUC=5 carboplatin (n=43) or to observation (n=39). The primary endpoint was disease free survival (DFS). The second endpoint was overall survival, response rate in the chemo group and safety. Analysis was by intention to treat. This trial was closed early by the EC as adjuvant chemotherapy became a standard therapy for resected NSCLC in 2005.

Results: 43 patients in the chemotherapy group and 39 in the observation group received their assigned treatment. 45 (54.9%) patients had stage IB disease, 20 (24.4%) had stage II disease, and 17 (20.7%) had stage IIIA disease. Adenocarcinoma accounted for 62.2% (51 cases, Tab.1). The median chemotherapy cycles were 3. After a median follow-up of 29.5 months (range 3-51), median disease free survival time is not reached in the chemotherapy group and 34 months in the observation group (p=0.0173). Median overall survival in both groups is not reached (Fig.1).



Conclusion: Adjuvant docetaxel plus carboplatin extends disease free survival in patients with completely resected NSCLC.

P2-222 **NSCLC: Combined Modality Therapy Posters, Tue, Sept 4**

Can the patients with locally advanced non-small cell lung cancer (LANSCLC) tolerate 60mg/m^2 docetaxel on day 1 and 30mg/m2 Cisplatin on day 1 and 2 for 2 cycles during concurrent radiotherapy (CCRT) after 2-3 cycles of induction chemotherapy?

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Background: CCRT plus consolidation chemotherapy is a standard treatment of LANSCLC. But there is still a great controversy about the chemotherapy regimen for CCRT. A group of physician in Korean found 20mg/m^2 docetaxel plus 20mg/m^2 cisplatin, weekly is maximum tolerated dose for patients with LANSCLC during 6 weeks of 63Gy radiotherapy. The purpose of our trial was to determine whether the NSCLC patients after 2-3 cycles of induction chemotherapy can tolerate the chemotherapy regimen of 60 mg/m^2 T and 60mg/m^2, 2 cycles in 6 weeks radiotherapy, based on toxicity.

Methods: Previously untreated 9 patients with histological/cytologically proven Stage III non-small-cell lung cancer were eligible after induction chemotherapy for 2-3 cycles. Followed a month later by continual radiotherapy (62-70Gy in 31-35 fractions, 6-7weeks) delivered concurrently with cisplatin and docetaxel. The dosage of level 1 was of 56 mg/m^2 docetaxel, on day 1 and 28mg/m^2 cisplatin, on day 1 and day 2, 2 cycles during CCRT. The radiotherapy model was conformal radiotherapy or intensity modulated radiotherapy. The dosage of level 2 was 60 mg/m^2 docetaxel, on day 1 and 30 mg/m^2 on day 1 and day 2. Response rate was evaluated as complete remission (CR), partial remission (PR), stable disease (SD) and progressive disease (PD).

Results: Nine patients were enrolled, with median age of 58, (43-70). Seven patients were male, 2 female. The ECOG scores of 4 patients were 0, and ECOG scores of 5 patients were 1. The loss of weight of 8 patients was 0%, that of one patient was ≤5% in three months before diagnosis. Seven patients were with squamous cell carcinoma, 2 with adenocarcinoma. The objective response was as follows: PR 8/9, SD 1/9. The toxicities were showed in table 1.

Conclusions: The patients with LANSCLC can tolerate 60mg/m^2 docetaxel and 60mg/m^2 cisplatin for 2 cycles during concurrent radiotherapy after 2-3 cycles of induction chemotherapy.

Table 1.. Nonhemotological toxicity

DL	NP	Fatigue				Leukocytes				Esophagitis				Nausea				Vomiting				Cough				Platelets				Pneumonitis			
		Grade (NCI Toxicity criteria 3.0)																															
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	2	3	4	2	1	2	3	4
1	6	4	2	-	-	-	4	1	1	4	2	-	-	2	1	-	-	2	1	-	-	5	1	-	-	1	-	-	1	-	1	-	-
2	3	2	1	-	-	1	1	1	-	2	1	-	-	2	-	-	-	2	-	-	-	2	1	-	-	-	-	-	-	-	-	-	-

DL: Dose level; **NP:** number of patients

P2-223 **NSCLC: Combined Modality Therapy Posters, Tue, Sept 4**

Analysis of clinical and dosimetric factors associated with severe radiation pneumonitis in locally advanced Non-Small-Cell-Lung-Cancer patients treated with concurrent chemotherapy and intensity-modulated radiotherapy (IMRT)

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Purpose: To retrospectively evaluate clinical and dosimetric factors associated with severe (grade≥3) radiation pneumonitis in patients after concurrent chemotherapy and intensity-modulated radiotherapy (IMRT).

Methods: We retrospectively analyzed 94 locally advanced NSCLC patients treated with concurrent chemotherapy and IMRT between May 2005 and September 2006. Radiation pneumonitis was graded according to Common Terminology Criteria for Adverse Events version 3.0. The following clinical parameters were considered: gender, age, smoking and diabetes history, history of chronic obstructive pulmonary disease (COPD), induction chemotherapy, concurrent chemotherapy regimens, performance status and forced expiratory volume in 1 second (FEV1). Dosimetric factors including mean lung dose (Dmean), rV5-V60 relative volumes of lung receiving more than a threshold dose D of radiation (rVD), where values of D considered were 5˚C 60 Gy in increments of 5 Gy), prescribed dose (63GY/35f/7w vs 60Gy/30f/6w), and normal tissue complication probability (NTCP) values were analysed. DVHs data and NTCP values were collected for both lungs considered as a parallel organ. Pearson Chi-Square test was performed to compare clinical parameters between patients who developed severe RP and those who did not. Univariate and multivariate logistic regression analyses were performed to evaluate data for association between clinical and dosimetric factors and severe RP. The study was approved by the institutional reviewboard.

Results: Of 94 patients, 11 (11.7%) develop severe (grade≥3) radiation pneumonitis; 6 (6.4%), grade 3; 2(2.1%), grade 4; and 3 (3.2%)grade 5. Univariate analyses show that Sex, age (≤60vs>60), smoking and diabetes history, induction chemotherapy, concurrent chemotherapy regimens, PS(≤70vs>70) and prescribed dose did not significantly differ between patients who developed severe RP and those who did not. However, NTCP, MLD, rV5-V60, COPD and FEV1 were associated with severe RP ($p<0.05$). In multivariate analysis, NTCP ($p=0.001$) and rV10($p=0.015$) was the most significant factors associated with severe (grade≥3) radiation pneumonitis. The incidences of Grade≥3 pneumonitis in the group with NTCP>4.2% and NTCP <4.2% were 43.5% and 1.4%, respectively ($p<0.01$). The incidences of Grade≥3 pneumonitis in the group with rV10 <51.2% and rV10 >51.2% were 5.6% and 30.4%, respectively ($p<0.01$).

Conclusions: NTCP and rV10 is useful indicator of risk for development of severe (grade≥3) radiation pneumonitis in NSCLC patients after concurrent chemotherapy and intensity -modulated radiotherapy (IMRT).

NSCLC: Cytotoxic Chemotherapy

P2-224 **NSCLC: Cytotoxic Chemotherapy Posters, Tue, Sept 4**

A multicenter phase II randomized study of paclitaxel (P) and carboplatin (C) versus oral vinorelbine (oV) and carboplatin (C) as second-line treatment in patients with non-small cell lung cancer (NSCLC) pretreated with non-platinum based chemotherapy

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Background: Limited data is available on the activity of platinum-containing doublets as second-line treatment of NSCLC patients who received non-patinum based first-line therapy. We performed a multicenter randomized phase II trial to compare PC and oVC in NSCLC patients (pts) pretreated with first-line docetaxel (D)/gemcitabine (G).

Methods: Pts with stage IIIB/IV NSCLC and adequate performance status (PS), haematological, hepatic, cardiac and renal function pretreated with DG were eligible. Pts received P 140 mg/m^2 combined with C AUC3 or oV 45 mg/m^2 combined with C AUC3 on days 1 and 15 of a 30-day cycle. Stratification was done for PS and response to prior treatment. Primary endpoint was response rate (RR) and secondary endpoints were time to progression (TTP), survival and toxicity.

Results: 140 pts were randomized to PC (n= 65) or oVG (n= 75). Median age was 60 yrs for both arms (range, 39-74 and 38-79, respectively) and PS was 0-1 in 91% and 85%, for PC and oVC, respectively. In an intension-to-treat analysis, significantly more responders were observed in the PC arm with an overall RR of 19.4% vs 4.2% ($p=0.006$). After a median follow up time of 5.4 (range 0.5-30) months, median TTP was 3.2 (range, 0.5-23.7) vs 2.8 (range, 0.5-18.5) for PC and oVC, respectively ($p=0.150$). Median overall survival was 6.3 (range, 0.5–26.2) vs 6.1 (range, 0.5–30) months and 1-yr survival was 29.4% vs 27.5% for PC and oVC, respectively ($p=0.586$). The two arms exhibited similar rates of grade 3 and 4 toxicity.

Conclusions: A higher response rate that was not translated to a survival benefit was recorded for the PC arm. No significant differences in toxicity rates were observed.

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A phase II trial of weekly cisplatin and docetaxel in advanced non-small cell lung cancer (NSCLC)

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Background: Every 3-week cisplatin doublets used to treat advanced NSCLC carry a significant risk of renal and other toxicities and can

